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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/751,087 | 01/02/2004 | Michael E. Hawkins | ZIM0398 | 1328 |

7590 03/01/2007
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| EXAMINER |
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RAMANA, ANURADHA

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| ART UNIT | PAPER NUMBER |
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3733

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS | 03/01/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | | | |
|------------------------------|-------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/751,087 | Applicant(s) HAWKINS, MICHAEL E. | |
| | Examiner Anu Ramana | Art Unit 3733 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 12, 13, 18 and 22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 12 and 13 is/are rejected.
- 7) ☒ Claim(s) 18 and 22 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The finality of the last office action is being withdrawn in view of the new rejections made in this office action. The indicated allowability of claim 1 is withdrawn in view of the rejections made in this office action. The Examiner apologizes for any inconvenience caused to the Applicant by this action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 13 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. The specification discloses condylar components joined by a pin or permanently joined together at the time of manufacturing and supplied as a one piece tibial bearing insert. Thus, the subject matter of claim 13 is deemed to be new matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 9 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Neil et al. (US 6,709,461) in view of Krebs et al. (US 6,365,089).

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O'Neil et al. disclose a tibial knee implant including: a first bearing component 14 made of a first material such as polyethylene; a second bearing component 12 made of second material such as polyethylene; an intercondylar component 36; and a pin 16 extending through the first bearing component, the second bearing component and the intercondylar component (Figs. 6 and 9, col. 4, lines 40-51, col. 5, lines 39-67, col. 6, lines 1-5 and lines 57-67 and col. 7, lines 1-45).

Regarding claim 9, O'Neil et al. disclose that the first bearing component 14 is made of the same material as the tibial tray 82 such as metal or polymer.

Regarding claim 12, O'Neil et al. disclose that the prosthesis system may include a variety of components present in different sizes to render them useful for different patient conditions wherein kits provided to surgeons may include a sufficient number of components to allow assembly of the prosthesis (col. 3, lines 27-35).

O'Neil et al. disclose all elements of the claimed invention except for the intercondylar component being made of a second material having a toughness value greater than the first material.

Krebs et al. teach restricting crosslinking to articulating surfaces of a tibial insert for improved wear resistance while maintaining higher mechanical properties, i.e., toughness, in the non-articulating areas of the insert such as the stabilizing post (col. 7, lines 37-64).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have crosslinked the articulating areas of bearing component 12, as taught by Krebs et al., to provide better wear characteristics.

Regarding claims 6 and 7, the combination of O'Neil et al. and Krebs et al. discloses the claimed invention except for the second material being a polymeric material such as polyketone or the first and second materials being different types or classes of polymeric materials. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have made the second bearing component of a polymeric material such as polyketone, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of

its suitability for the intended use, herein a biocompatible polymeric material, as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Regarding claim 9, the combination of O'Neil et al. and Krebs et al. discloses the claimed invention except for the first material being a ceramic. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have made the first bearing component of a ceramic, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use, herein a biocompatible engineering material of suitable strength and stiffness, as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claims 1-2, 7-9 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Neil et al. (US 6,709,461) in view of Moser (US 5,123,928).

O'Neil et al. disclose a tibial knee implant including: a first bearing component 14 made of a first material such as polyethylene; a second bearing component 12 made of second material such as polyethylene; an intercondylar component 36; and a pin 16 extending through the first bearing component, the second bearing component and the intercondylar component (Figs. 6 and 9, col. 4, lines 40-51, col. 5, lines 39-67, col. 6, lines 1-5 and lines 57-67 and col. 7, lines 1-45).

Regarding claim 9, O'Neil et al. disclose that the first bearing component 14 is made of the same material as the tibial tray 82 such as metal or polymer.

Regarding claim 12, O'Neil et al. disclose that the prosthesis system may include a variety of components present in different sizes to render them useful for different patient conditions wherein kits provided to surgeons may include a sufficient number of components to allow assembly of the prosthesis (col. 3, lines 27-35).

O'Neil et al. disclose all elements of the claimed invention except for the intercondylar component being made of a second material having a toughness value greater than the first material.

Moser teaches strengthening an intercondylar post of a knee prosthesis by coating it with metal (Fig. 1c and col. 2, lines 35-38).

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to have coated the intercondylar post of the O'Neil et al. tibial implant with metal, as taught by Moser, to strengthen the post.

Regarding claim 9, the combination of O'Neil et al. and Moser discloses the claimed invention except for the first material being a ceramic. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have made the first bearing component of a ceramic material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use, herein a biocompatible engineering material of suitable strength and stiffness, as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Allowable Subject Matter

Claims 18 and 22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AR
February 26, 2007

Annabella Ramare
1/26/07